APR 13 2005

K050038
1 of 1

510(k) Summary

Submitter: Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403
USA

Contact Person: Willie Mitchell
Associate Regulatory Affairs Specialist
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Date Prepared: January 6, 2005

Trade Name: Reliant Stent Graft Balloon Catheter

Common Name: Balloon Catheter

Classification Name: Percutaneous Catheter

Predicate Devices: The CODA Balloon Catheter (K032869) manufactured by Cook Incorporated (vessel occlusion and expansion of vascular prosthesis, product code DQY), and was cleared by FDA on November 19, 2003.

The Iliac Balloon Catheter (K003495) manufactured by Guidant Corporation (prosthesis expansion, product code DQY), and was cleared by FDA on February 7, 2001.

The Large Diameter Occlusion Balloon Catheter (K002286) manufactured by Cook Incorporated (vessel occlusion, product code MJN), and was cleared by FDA on March 22, 2001.

Substantial Equivalence: The Reliant Stent Graft Balloon Catheter is substantially equivalent to the predicate devices listed above, as it is comparable with respect to their intended use, overall catheter configuration, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2005

Medtronic Vascular
c/o Mr. Willie Mitchell
Associate Regulatory Affairs Specialist
3576 Unocal Place
Santa Rosa, CA 95403

Re: K050038
Reliant Stent Graft Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: January 6, 2005
Received: January 7, 2005

Dear Mr. Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Volkmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): not yet assigned K050038

Device Name: Reliant Stent Graft Balloon Catheter

Indications For Use:

The Reliant Stent Graft Balloon Catheter is intended for temporary occlusion of large vessels, or to expand vascular prostheses.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050038